

II. REMARKS

This paper is filed with a Request for Continued Examination, Petition for Three (3) Month Extension of Time, and the required fees. The Office Action dated July 16, 2010 has been carefully reviewed.

Claims 13-15, 19-21, 24-27, and 30-36 are pending and rejected.

By this Amendment, claims 13, 33, and 24 are amended, and claims 21, 24-27, 30-32, 35, and 36 are canceled. Support for the amendment can be found in the specification and claims as original filed. For example, support for the amendment to claim 1 can be found in canceled claims 21 and 25. Applicants submit that no new matter has been added and respectfully request reconsideration and withdrawal of the pending rejection.

Rejection under 35 U.S.C. § 103(a)

Claims 13-15, 18-21, 24-27, and 30-36 are rejected under 35 U.S.C. §103(a) as being obvious over Okamoto (machine translation of Japanese Patent No. JP 10-218787, hereinafter "Okamoto"). Applicants traverse the rejection.

Presently amended claim 13 is directed to a "method for the treatment of a pathology affecting tissues of an eye selected from the group consisting of: sclera, ciliary bodies, crystalline lens, retina, optic nerve, vitreous body, and choroidea, comprising: (1) identifying a subject in need of treatment of the pathology, (2) topically applying a composition comprising from 200 to 500 µg/ml of nerve growth factor over an ocular surface of the subject, and contacting the tissues with the nerve growth factor to treat the pathology, wherein the pathology is selected from the group consisting of: cataract, optic neuritis, glaucoma, maculopathy, retinitis pigmentosa, myopic retinopathy, macular foramen, uveitis, vitrectomy, ocular hypotonia, scleromalacia, perforating trauma of the sclera, and phthisis" (emphasis added). Claims 14, 15, 18-20, 33, and 34 depend from claim 13. As noted above, claims 21, 24-27, 30-32, 35, and 36 are canceled.

Applicants submit that Okamoto does not teach or suggest the claimed invention. Okamoto discloses ophthalmic compositions comprising a neurotrophic factor NGF (see

abstract). Okamoto discloses that a concentration of NGF of 10 µg/250 mL to 0.1 µg to 100 mg/250 mL (may be used” (paragraph [0051], machine translation). Applicants note that 10 µg/250 mL is 0.04 µg/mL; and 1 µg to 100 mg/250 mL is 0.004 µg to 400 µg/mL.

Applicants submit that based on the teachings of Okamoto and without the benefit of hindsight, one of ordinary skill in the art would not understand the unexpected results of the claimed invention. In particular, one of ordinary skill in the art would not understand that at the dose of 0.04 µg/mL (the exemplified dose in Okamoto), nerve growth factor would not pass through, for example, the retina or optic nerve). In addition, based on the teachings of Okamoto, one of ordinary skill in the art would not understand that at the claimed doses range of “200 to 500 µg/mL,” one could effectively treat the recited pathologies of the eye.

For at least the above reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 13-15, 18-21, 24-27, and 30-36 under 35 U.S.C. § 103(a) over Okamoto.

Double Patenting Rejection

Claims 13, 15, 18-21, 24-27, 30, 31, 33, 35, and 36 are provisionally rejected on the ground of nonstatutory obviousness-type patenting as being unpatentable over claims 1, 8-11 and 13 of copending Application No. 12/064,172 (hereinafter “the ‘172 application”). Applicants traverse the rejection.

As noted previously, Applicants submit that the ‘172 application, which claims priority to a PCT application filed on August 11, 2006, would unlikely expire before the expiration of the present application, which claims priority to a PCT application filed on January 21, 2000. Applicants submit that it is inappropriate to require the filing of a Terminal Disclaimer, as it is unclear what claims will be allowed in the ‘172 application. In addition, claims of the ‘172 application are directed to methods “for the therapy and/or prophylaxis of pathologies affecting the central nervous system.” Applicants note that the recited pathologies in the present claims are ophthalmic conditions and not

conditions of the central nervous system. In particular, Applicants submit that the optic nerve is a peripheral nerve which is not part of the central nervous system.

The Examiner cites Okamoto as evidentiary reference showing that topically administered NGF is known to be useful in the treatment of the optic nerve due to intracranial disease. In particular, the Examiner cites claim 7 of Okamoto, which recites that optic nerve compression can result from "optic canal fracture or a tumor in an eye socket, or an artery varix, intracranial disease, brain tumor, a hypophyseal tumor, bleeding, and infarction." Applicants respectfully submit that the cited passages of Okamoto are irrelevant, as optic neuritis is not a disease of the nervous system, and the optic nerve is not a cranial nerve. In fact, Okamoto in paragraph [0037] lists examples of cranial nerve diseases (Alzheimer's, demyelination diseases of the nervous system, autoimmune disease, multiple sclerosis, and amyotrophic lateralsclerosis), and optic neuritis is not one of the named conditions.

For at least the above reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 13, 15, 18-21, 24-27, 30, 31, 33, 35, and 36 on the ground of nonstatutory obviousness-type patenting as being unpatentable over claims 1, 8-11 and 13 of the '172 application.

III. **CONCLUSION**

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event this response is not timely filed, the Applicants hereby petition for an appropriate extension of time. The fee for this extension, along with any other additional fees which may be required with respect to this response, may be charged to Deposit Account No. **01-2300**, referencing Attorney Docket No. **026073-00020**.

Respectfully submitted,



Yelee Y. Kim
Registration No. 60,088

Customer No. 004372
Arent Fox LLP
1050 Connecticut Avenue, N.W., Suite 400
Washington, D.C. 20036-5339
Tel: (202) 857-6000
Fax: (202) 857-6395

RJB/YYK:yyk